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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/281,430 03/30/99 PARIKH

I 121-160

HM12/0717

EXAMINER

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WARE, T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED:

07/17/00

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>09/281,430</b>	Applicant(s) <b>Parikh et al</b>
	Examiner <b>Todd D. War</b>	Group Art Unit <b>1615</b>

Responsive to communication(s) filed on Sep 27, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claim

Claim(s) 1-21 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-21 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

- received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 4&5

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

**-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --**

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## DETAILED ACTION

Receipt of declaration filed 5-13-99, information disclosure statement filed 6-9-99 and the information disclosure statement filed 9-27-99 is acknowledged.

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, and 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Recitation of “derivatives thereof” in claim 1 is indefinite since it is not specified what the derivatives are. Derivatives of compounds are considered “so indefinite as to be meaningless” since they “cover such a large number of compounds, whose structures are not defined, that the specification does not support the claims” (Petrolite v. Watson, Comr. Pats. 113 USPQ 248, 1957). In the instant application, the specification does mention derivatives of the fatty acid esters but does not define what derivatives the claims are intended to encompass.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaufman et al (WO 96/02247; hereafter '247).

'247 discloses stable taxane anticancer emulsions comprising non-ionic surfactants, oils and ethanol.

5. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Lundberg (1997). Lundberg discloses stable paclitaxel anticancer emulsions comprising non-ionic surfactants, oils and ethanol.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al (WO 96/02247; hereafter '247) in view of Sime et al (WO 96/35415; hereafter '415) or Lundberg (1997) in view of Sime et al (WO 96/35415; hereafter '415).

'247 and Lundberg both teach stable taxane anticancer emulsions comprising non-ionic surfactants, oils and ethanol. They do not teach inclusion of a P-450 or glycoprotein transport system inhibitor.

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‘415 is relied upon for teaching the inclusion of a sesquiterpene derived from grapefruit juice to decrease the metabolism of anticancer agents such as taxanes.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to include the sesquiterpene of ‘415 in either the composition of ‘247 or Lundberg with the expectation that doing so would increase the duration of action of the taxane; the motivation being to decrease the frequency of administration of the taxane.

8. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al (WO 96/02247; hereafter ‘247) in view of Benita et al (5,965,160; hereafter ‘160) or Lundberg (1997) in view of Benita et al (5,965,160; hereafter ‘160).

‘247 and Lundberg are relied upon for all that they teach as stated above. Additionally, both ‘247 and Lundberg teach that the resulting droplets are less than 10 $\mu$ m and that the oils (hydrophobic component) are present in amounts between 15 and 75%. Neither ‘247 or Lundberg teach inclusion of surfactants in amounts between 20 and 80%.

‘160 is relied upon for teaching hydrophilic-hydrophobic microemulsions that spontaneously emulsify comprising surfactants in amounts within applicants’ ranges to maintain the stability of the emulsions.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to include greater amounts of surfactants in the compositions of ‘247 or Lundberg in an effort to maintain the stability of the emulsions of ‘247 or Lundberg with the expectation that increasing the amount of surfactants would do so.

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9. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al (WO 96/02247; hereafter '247) in view of Charman et al (5,968,987; hereafter '987) or Lundberg (1997) in view of Charman et al (5,968,987; hereafter '987).

'247 and Lundberg are relied upon for all that they teach as stated above. Additionally, both '247 and Lundberg teach that the resulting droplets are less than 10 $\mu$ m and that the oils (hydrophobic component) are present in amounts between 15 and 75%. Neither '247 nor Lundberg teach inclusion of surfactants in amounts between 20 and 80%.

'987 is relied upon for teaching hydrophilic-hydrophobic microemulsions that spontaneously emulsify comprising surfactants in amounts within applicants' ranges to maintain the stability of the emulsions.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to include greater amounts of surfactants in the compositions of '247 or Lundberg in an effort to maintain the stability of the emulsions of '247 or Lundberg with the expectation that increasing the amount of surfactants would do so.

### ***Conclusion***

10. Currently, no claim is allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on Monday through Friday from 8 AM to 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235 or 308-1234.

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

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7-12-00